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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,790	04/21/2004	Igor Dimitriesich Polyakov	3/400-5-C5	5045

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EXAMINER	
MINNIFIELD, NITA M	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,790	POLYAKOV ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 3 sheets

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/23/04*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-6 are pending in the present application.

2. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a dermatomycosis vaccine comprising antigenic material from at least one of the inactivated dermatophytes as set forth in claim 1 (8 dermatophytes), as set forth in claim 2 (3 dermatophytes). Claims 3 and 4 also recite the source of the antigenic material used in the vaccine. The specification does not set forth enablement of a vaccine comprising 4 or more inactivated dermatophyte strains. Examples 1-3 and Tables 9-10 have been reviewed. It is not clear what Applicants used in the vaccine composition. Example 1, page 18 indicates that "[A]fter 2 days, 125 ml of each culture in suspension is taken and mixed in a single container. The vaccine may be prepared by mixing together various combinations of the given strain." Exactly what was the composition of the vaccine administered that gave the results found in Tables 9 and 10? It is not clear if all 8 dermatophytes were used or some combination of 3, 4, 6 or 7 dermatpohytes. It is not clear that the specific combination of 3 dermatophytes as set forth in claim 2 were used. It is not clear what dermatophytes in the vaccine gave rise to the vaccine protection that is shown in Table 10. Does Applicant intend for "immunogenic response" to mean that vaccine protection has been

established, see page 11, or "establishing immunity" to mean vaccine protection has been established, see Tables 1-7?

The specification has not taught how to use the claimed vaccine. Mixing each culture in a single container or mixing together various combinations of the given cultures is set forth. However, it is not clear which composition (all 8 cultures in one container or various combinations of less than 8 cultures and if less than 8 cultures specifically which ones) was used to generate the data found on tables 9 and 10 of the specification. Which cultures provide protection against ringworm infection in an animal? Does the vaccine comprising a combination of cultures protect in the same manner as the individual cultures; is there a synergistic affect with regard to protection against ringworm infection?

There does not appear to be support or enablement for a vaccine consisting of just one antigen from one dermatophyte or a vaccine consisting of just one dermatophyte, *T. verrucosum*. The art teaches the use of multiple dermatophytes in a vaccine composition, not a single dermatophyte, or single antigen from a single dermatophyte (Pier et al, 1995, 5284652; Sarkisov et al 4368191).

Gudding et al (Can. Vet. J., 1995) teaches that in animals vaccinated with inactivated vaccines, some protection is observed after challenge. However, the protective immunity is inadequate in most cases (abstract; p. 303, column 2). Further, the inactivated vaccine against ringworm must be capable of eliciting both humoral and cellular immune responses, of which the cellular response is crucial for protection and adjuvants are important in stimulating the cellular branch of the immune system (pp. 303-304). In view of the state of the art it is not clear if protection has been established against ringworm infection when Applicants state (see tables 1-7) "establishes immunity". It is not clear what type of immunity has

been established. Applicants' vaccine composition does not recite a carrier or adjuvant, however Gudding indicates that the adjuvants are important in stimulating the cellular branch of the immune system and that the cellular branch is crucial for protection.

In view of the above discussion, there would be undue experimentation necessary for a person of skill in the art to practice the claimed invention.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of

copending Application No. 10/085703. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a dermatomycosis vaccine comprising inactivated dermatophyte strains.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wawrzkiewicz et al, 1991 (Med. Weter., 47/7:317-320). Abstract only

Wawrzkiewicz et al discloses an inactivated vaccine against trichophytosis (ringworm), and that the vaccine comprises inactivated *T. verrucosum*.

8. Claim 1 is rejected under 35 U.S.C. 102 (e) as being anticipated by Pier 5277904.

Pier discloses a vaccine (and the preparation of a vaccine) for the prophylaxis or dermatophyte infection in animals using *T. mentagrophytes*, *M. canis*, and *M. gypseum* (abstract; claims; col. 3, l. 43 to col. 8, l. 58; examples). Pier discloses a novel, broad-spectrum vaccine for vaccination of cats, dogs, livestock and fur-bearing animals against contagious infections caused by dermatophytes (col. 1). The prior art discloses the claimed invention.

9. Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Werner et al 5453273, Werner et al 6132733, Strobel et al 6428789 or Strobel et al 6723328.

Strobel et al, 6723328 for example, discloses a ringworm vaccine comprising inactivated (formaldehyde-killed) *Microsporum canis, Microsporum gypsum,* or *Trichophyton mentagrophytes* (abstract). Strobel et al discloses a list of dermatophytes and the hosts that they infect (Table 1). The antigen can be a single protein (i.e. antigenic material) from a dermatophyte or a plurality of antigens (cols. 2-3) as well as the cells (col. 4).

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sarkisov et al 4368191 or Woloszyn et al 1983 (Med. Weter., 1983, 39/7:387-391 Abstract only).

Woloszyn et al, for example, discloses inactivated strains of T. mentagrophytes (abstract).

11. With regard to the art rejections, it is noted that the recitation of "vaccine" is viewed as intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Since the Patent Office does not have the facilities for examining and comparing applicants' vaccines with the vaccines of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed vaccines and the vaccines of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

12. No claims are allowed.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is

571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
September 24, 2004